CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number 74-898

Trade Name Iopamidol 200ml, 250ml, 300ml, 370ml, 500ml

Generic Name Iopamidol 200ml, 250ml, 300ml, 370ml, 500ml

Sponsor Abbott Laboratories

Indications for angiography throughout the cardivascular system including cerebral and peripheral arteriography, coronary arteriography and ventriculography, pediatric angiocardiography, selective visceral arteriography and aortography, peripheral venography, and adult and pediatric intravenous excretory urography and intravenous adult and pediatric contrast enhancement of computed tomography (CECT) head and body imaging.

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APPLICATION 74898

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)				
Statistical Review(s)				
Microbiology Review(s)				
Clinical Pharmacology Biopharmaceutics Review(s)				
Bioequivalence Review(s)	X			
Administrative Document(s)	X			
Correspondence				

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Application Number 74898

APPROVAL LETTER

ANDA 74-898

30 JUL

Abbott Laboratories
Attention: Thomas F. Willer, Ph.D.
200 Abbott Park Road, D-389 AP30
Abbott Park, Illinois 60064-3537

Dear Sir:

This is in reference to your abbreviated new drug application dated April 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Iopamidol-200, Iopamidol-250, Iopamidol-300, and Iopamidol-370, (Iopamidol Injection USP, 41%, 51%, 61%, and 76% respectively (Pharmacy Bulk Packages) packaged in flexible plastic containers.

Reference is also made to your amendments dated December 20, 1996; and September 5, December 4, and December 10, 1997.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Iopamidol Injection USP, 41%, 51%, 61% and 76% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Isovue® Multipak™-200, Isovue® Multipak™-250, Isovue® Multipak™-300, Isovue® Multipak™-370, respectively, of Bracco Diagnostics Inc).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research